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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,601	03/15/2001	Stephen Donovan	D-2947CIP	9283

7590 08/22/2002

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/810,601

Applicant(s)

DONOVAN, STEPHEN

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-21, drawn to an agent, comprising a light chain component comprising a light chain or a fragment thereof of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; a translocation component comprising a heavy chain or a modified heavy chain of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; and a targeting component which selectively binds to a GnRH receptor, classified in class 530, subclass 350, and class 424, subclass 239.1.

Should Group I be elected, applicant is required to select one amino acid sequence from claim 12 or 14, and the sequence is identified by a "SEQ ID NO:" with each amino acid residue defined at each position. Any change of amino acid residue at any one or more positions is considered, absent factual data to the contrary, a distinct peptide. This is not a species election.

II. Claims 22 and 23, drawn to a method for treating a gonadotrophin related illness in a mammal, comprising administering to the mammal an agent which comprises a light chain component comprising a light chain or a fragment thereof of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; a translocation component comprising a heavy chain or a modified heavy chain of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; and a targeting component which selectively binds to a GnRH receptor, wherein the gonadotrophin related illness is breast cancer,

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prostate cancer, pancreatic cancer or endometrial cancer, classified in class 530, subclass 350, and class 424, subclass 239.1.

III. Claims 22-24, drawn to a method for treating a gonadotrophin related illness in a mammal, comprising administering to the mammal an agent which comprises a light chain component comprising a light chain or a fragment thereof of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; a translocation component comprising a heavy chain or a modified heavy chain of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; and a targeting component which selectively binds to a GnRH receptor, wherein the gonadotrophin related illness is precocious puberty, classified in class 530, subclass 350, and class 424, subclass 239.1.

IV. Claims 22-23 and 25, drawn to a method for treating a gonadotrophin related illness in a mammal, comprising administering to the mammal an agent which comprises a light chain component comprising a light chain or a fragment thereof of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; a translocation component comprising a heavy chain or a modified heavy chain of a botulinum toxin, a butyricum toxin or a tetani toxin or variants thereof; and a targeting component which selectively binds to a GnRH receptor, wherein the gonadotrophin related illness is endometriosis, classified in class 530, subclass 350, and class 424, subclass 239.1.

2. The inventions are distinct, each from the other because of the following reasons:

The product of Invention I and the methods of Inventions II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions II-IV are alternative processes of use of the product of Invention I.

The methods of Inventions II, III and IV are distinct from each other because the method steps, the material used and the outcomes are wholly different among Inventions II-IV, thus, Inventions II, III and IV are patent distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because Inventions I-IV require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

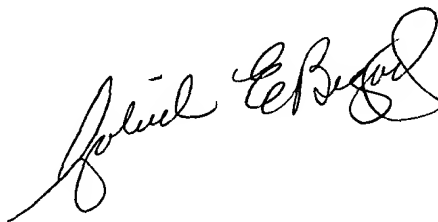
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

August 20, 2002



GABRIELLE BUGAISKY
PRIMARY EXAMINER